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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,532	11/21/2003	David Follansbee	DAVFOL.002C1	3410

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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,532	FOLLANSBEE, DAVID	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3-6 and 8, drawn to a pharmaceutical formulation for preventing or treating allergies comprising an isolated protein, classified in class 530, subclass 350 and class 424, subclass 184.1.

II. Claim 7, drawn to a pharmaceutical formulation for preventing or treating allergies comprising an effective amount of a nucleic acid, classified in class 536, subclass 23.1 and class 514, subclass 44.

III. Claims 9-10, drawn to a pharmaceutical formulation for preventing or treating allergies comprising an antibody, classified in class 530, subclass 387.1 and class 424, subclass 134.1.

IV. Claims 13-15 and 17-19, drawn to a method of preventing or treating allergies or asthma comprising administering a therapeutically effective dose of an isolated protein, classified in classified in class 530, subclass 350 and class 424, subclass 184.

V. Claims 13-15 and 17-19 drawn to a method of preventing or treating allergies or asthma comprising administering a therapeutically effective dose of a nucleic acid, classified in class 536, subclass 23.1 and class 514, subclass 44.

VI. Claims 13-15 and 17-19 drawn to a method of preventing or treating allergies or asthma comprising administering a therapeutically effective dose of an antibody, classified in class 530, subclass 387.1 and class 424, subclass 134.1.

VII. Claims 16 and 21-24, drawn to a method of immunizing a human against IgE-regulated allergic reactions with an isolated protein, classified in class 530, subclass 350 and class 424, subclass 184.1.

VIII. Claims 16 and 21-24, drawn to a method of immunizing a human against IgE-regulated allergic reactions with a nucleic acid, classified in class 536, subclass 23.1 and class 514, subclass 44.

IX. Claims 16 and 21-24, drawn to a method of immunizing a human against IgE-regulated allergic reactions with an antibody, classified in class 530, subclass 387.1 and class 424, subclass 134.1.

X. Claim 20, drawn to a method of competitively inhibiting allergen-specific IgE by administering an isolated protein, classified in class 530, subclass 350 and class 424, subclass 184.1.

XI. Claim 20, drawn to a method of competitively inhibiting allergen-specific IgE by administering a nucleic acid, classified in class 536, subclass 23.1 and class 514, subclass 44.

XII. Claim 20, drawn to a method of competitively inhibiting allergen-specific IgE by administering an antibody, classified in classified in class 530, subclass 387.1 and class 424, subclass 134.1.

2. Claims 1, 2, 11 and 12 link inventions I-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims 1, 2, 11 and 12. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Groups I, II, and III are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

4. Groups IV- XII are different methods. The method of Groups IV-VI drawn to a method of preventing or treating allergies, of Groups VII-IX drawn to a method of immunizing a human against IgE-regulated allergic reactions and of Groups X-XII drawn

to a method of competitively inhibiting allergen-specific IgE differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

The methods of Groups IV-VI, VII-IX and X-XII are also distinct from one another due to differing active ingredients used for each method. For example, though Groups IV-VI are all directed to a method of preventing or treating allergies, the active ingredient is protein Group IV, nucleic acid in Group V and antibody in Group VI. Therefore all the methods are different.

5. Groups I- III and Groups IV-XII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used for affinity purification, in addition to the methods of treating recited. Likewise, the nucleic acids of Group II can be used for cloning and the protein of Group I can be used for generation of monoclonal antibodies.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the

structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 7, 2006

Maher M. Haddad
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PATENT EXAMINER
Primary

Nora M. Rooney, M.S., J.D.

Patent Examiner

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